K012746

NOV 1 4 2001

510(k) Summary
for
Behive Ltd
Ice Baton

1. SPONSOR

Behive Ltd
308 Abbey Road
Popley 4
Basingstoke Hants
England

Contact Person: Graham Holland
Telephone: 44 0 1256 326990

Date Prepared: August 15, 2001

2. DEVICE NAME

Proprietary Name: Ice Baton
Common/Usual Name: Hemorrhoid Device
Classification Name: Thermal Hemorrhoid Device

3. PREDICATE DEVICES

Cryotherapy Pain Relief Products, Inc.- AnuIce - K981428

4. DEVICE DESCRIPTION

The Ice Baton is a suppository-shaped medical device designed to provide relief from the pain and discomfort due to hemorrhoids. The Ice Baton consists of an applicator cover and applicator. During use, the cover is removed and the Ice Baton applicator is filled with bottled or drinking water. The applicator cover is placed back on the Ice Baton and excess water is removed. The Ice Baton is placed in the user's freezer until frozen.

After the Ice Baton is removed from the freezer, the applicator cover is removed and the Ice Baton is applied to the target hemorrhoid area. It is maintained on that area until the ice has melted or relief is felt. The Ice Baton is a disposable device.

5. INTENDED USE

The Ice Baton is intended to provide relief for pain and discomfort due to hemorrhoids.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Behive Ltd Ice Baton and the Cryotherapy Pain Relief Products, Inc. AnuIce are both intended for the same purpose, to provide relief for the pain and discomfort due to hemorrhoids by cooling the hemorrhoids.

The Ice Baton and AnuIce devices are similar in design and characteristics. Both devices include an applicator/tube and cap. The Ice Baton is filled with water whereas the AnuIce is prefilled with a coolant solution. The Ice Baton is a disposable device and the AnuIce is a reusable device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2001

Behive Ltd.
c/o Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K012746
Trade/Device Name: Behive Ltd. Ice Baton
Regulation Number: None
Regulatory Class: Unclassified
Product Code: 78 LKX
Dated: August 15, 2001
Received: August 16, 2001

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012746

510(k) Number (if known): K012746

NOV 1 4 2001

Device Name: Ice Baton

Indications For Use:

The Ice Baton is intended to provide relief from pain and discomfort due to hemorrhoids

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012746

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)